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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/852,154	05/09/2001	John J. Voorhees	1718-009B	3869

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EXAMINER

KIM, VICKIE Y

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 01/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/852,154	Applicant(s) VOORHEES ET AL.	
	Examiner Vickie Kim	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
 4a) Of the above claim(s) 5-18 and 20-34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 19 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>9/2002 & 6/2004</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Election acknowledged

1. Applicants' election with traverse the invention group I of claims 1-9, 18-19 and 21 is acknowledged. Applicants also elect NF-kB inhibitors(an indirect MMP inhibitor) and anti-inflammatories as the species of each component required for claimed combination composition.

It is noted that inclusion of claim 21 in the invention of group I is typographical error which is self evidenced by it's own description where the claimed subject matter is drawn to a composition whereas the claim 21 is directed to a method as well as the nature of group III which properly includes claim 21. Thus, acknowledgement is made of the election of the invention of group I where the election properly includes claims 1-9 and 18-19.

Applicants partial traverse the restriction requirement on the grounds that there would be no burden in searching the inventions of group I and V because each invention use the same active agent(i.e. NF-kB inhibitor). However, this argument is not persuasive, as each invention may not be anticipated by others because each invention is patentably distinct to each other as self evidenced its own description of the claimed subject matter, for instance Group I is drawn to a composition requiring a combination comprising NF-kB inhibitor and anti-inflammatories whereas group V is drawn to a method only requiring NF-kB inhibitor, and lack of anticipation for each invention is also evidenced by numerous patents(see US5095033, US4912096, US5684021, US5854290 or US5753693). For example, a composition can be practiced

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for materially different process of using and the method for treating acne can be practiced by materially different product such as retinoids, etc.

Furthermore, even if there were unity of classification, the search of the entire genus in the patent and non-patent(a significant part of a thorough examination) would be burdensome. Thus, each invention is found to be independent and patentably distinct, further burdensome.

Therefore, the restriction requirement is maintained, and made FINAL.

Status of Application

1. Upon entering the election, the claims 1-4, 19 (elected species) have been examined. If the elected species are found to be allowable, the examination will be extended to other claims with a next specie of choice until the elected invention of group I(claims 1-9, 18-19) are found to be all allowable.
2. The claims 1-34 are pending. All remaining claims not drawn to the elected invention are withdrawn from further consideration as being non-elected. The following rejections are made.

Information Disclosure Statement(IDS)

The information disclosure statement (IDS) is submitted on 6/18/2004 and 9/23/2002. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner. Please refer to applicants' copy of the 1449 submitted herewith.

Claim Rejections - 35 USC § 102

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3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-4 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Murad(US 5,972,999), Blank et al (US 5,605,894) or Bernard et al(US 5607921).

The claims 1-4 and 19 are drawn to a composition comprising a NF-kB inhibitor(an indirect MMP inhibitor) and an anti-inflammatory agent. The claim 3 additionally requires dermatologically acceptable carrier.

Murad(US'999 , hereinafter) teaches a pharmaceutical composition for prevention and treatment of unwanted skin conditions, wherein said composition comprises quercetin and vitamin E, see example 3. As stated in the US'999 patent at column 1, lines 66-67 and column 2, lines 60-62, vitamin E and ascorbic acid(vitamin C) are acting as anti-inflammatories. It is well known in the art that quercetin is inherently a NF-kB inhibitor and an indirect MMP inhibitor which are we, as evidenced by applicant's own admission, see instant specification at page 12, lines 30-32 and page 19, lines 28-34. US'999 further teaches that the patented composition can be formulated in various dosages forms suitable for not only systemic (e.g. oral , intravenous) administrations but also topical and transdermal administrations, see column 8, lines 50-59.

All the critical elements are well taught by the cited reference and thus, the claimed invention is not patentably distinct over the prior art of the record.

It is noted that the recitation(i.e. for reducing the occurrence of acne scarring) has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

Blank et al(US'894) teaches a composition for undesirable skin conditions, wherein the composition comprising (a) salicylic acid ; (b) an anti-inflammatory agent and (c) a pharmaceutically acceptable carrier, see claim 1.

As evidenced by applicant's own admission, salicylic acid is an effective NF-kB inhibitor(see instant specification at page 20, lines 8-10. And thus, the patented composition is well commensurate with the instant invention.

Bernard et al(US'921) teaches a composition for skin conditions, wherein the composition comprising (a) quercetin (b) tocopherol, ascorbic acid, or retinol, see claims 1 and 9. US'921 further teaches a dermatologically acceptable carrier, see column 5, lines 10-20. As mentioned earlier in 102 rejection over Murad(US'999),

tocopherol or ascorbic acid are well known anti-inflammatories, and thus the claimed invention is well anticipated by the cited reference(US'921).

Conclusion

1. US5411742(Sebag et al) is particularly pertinent to the claimed invention, see claims 1 and 11.
2. No claim is allowed.
3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vickie Kim whose telephone number is 571-272-0579. The examiner can normally be reached on Tuesday-Friday.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Chris Low be reached on 571-272-0953. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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 **VICKIE KIM**
PRIMARY EXAMINER

Vickie Kim

January 19, 2005

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